

What is claimed is:

1. A pharmaceutical composition comprising  
an aqueous carrier;  
from 0.1 mg/ml to 20 mg/ml of the composition of a  
pharmaceutically acceptable salt of a peptide having the  
structural formula  
NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH  
(SEQ ID NO:1); and  
a substituted  $\beta$ -cyclodextrin in an amount effective to  
dissolve the peptide in the aqueous carrier,  
wherein the composition has a pH between 4 and 9.
2. The pharmaceutical composition of claim 1, wherein the  
concentration of the salt of the peptide is at least 0.5  
mg/ml.
3. The pharmaceutical composition of claim 2, wherein the  
concentration of the salt of the peptide is from 0.5 mg/ml  
to 10 mg/ml.
4. The pharmaceutical composition of claim 3, wherein the  
concentration of the salt of the peptide is from 0.5 mg/ml  
to 2.5 mg/ml.
5. The pharmaceutical composition of any one of claims 1-4,  
wherein the composition has a pH between 6.5 and 8.5.
6. The pharmaceutical composition of claim 5, wherein the  
composition has a pH between 7.5 and 8.5.
7. The pharmaceutical composition of any one of claims 1-6,  
wherein the pharmaceutically acceptable salt is an acetate  
salt.

8. The pharmaceutical composition of any one of claims 1-7, wherein the substituted  $\beta$ -cyclodextrin is a hydroxypropyl, a sulfobutyl ether, or a sulfopropyl ether substituted  $\beta$ -cyclodextrin.
9. The pharmaceutical composition of claim 8, wherein the substituted  $\beta$ -cyclodextrin is a sulfobutyl ether substituted  $\beta$ -cyclodextrin.
10. The pharmaceutical composition of claim 7, wherein the substituted  $\beta$ -cyclodextrin is hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin.
11. The pharmaceutical composition of any one of claims 1-10, further comprising a pharmaceutically acceptable buffer in an amount and of a type suitable to make the pH of the pharmaceutical composition in the range of 4-9.
12. A pharmaceutical composition comprising  
an aqueous carrier;  
from 0.1 mg/ml to 20 mg/ml of the composition of an acetate salt of a peptide having the structural formula  
 $\text{NH}_2\text{-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH}$  (SEQ ID NO:1); and  
from 70 mg/ml to 170 mg/ml of the composition of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin,  
wherein the peptide and the hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin are dissolved in the aqueous carrier; and  
wherein the composition has a pH between 6.5 and 8.5.
13. The pharmaceutical composition of claim 12, wherein the concentration of the acetate salt of the peptide is at least 0.5 mg/ml.
14. The pharmaceutical composition of claim 13, wherein the

concentration of the acetate salt of the peptide is from 0.5 mg/ml to 10 mg/ml.

15. The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 to 2.5 mg/ml.
16. The pharmaceutical composition of claim 13, wherein the concentration of hepta-(sulfobutyl ether)- $\beta$ -cyclodextrin is 120 mg/ml, and wherein the pH of the composition is between 7.5 and 8.5.
17. The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 1.0 mg/ml.
18. The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 2.5 mg/ml.
19. A method of alleviating symptoms of systemic lupus erythematosus (SLE) in a human subject comprising administering to the human subject the pharmaceutical composition of any one of claims 1-18 in an amount effective to alleviate the symptoms of SLE in the human subject.
20. The pharmaceutical composition of any one of claims 1-18 for use in treating SLE in a human subject.
21. A process for manufacturing the pharmaceutical composition of any one of claims 1-18 comprising the steps of:
  - a) preparing a solution of a substituted  $\beta$ -cyclodextrin in an aqueous carrier at a predetermined concentration;

- b) adding a predetermined amount of a pharmaceutically acceptable salt of the peptide NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1) to the solution of step a);
- c) adjusting the pH of the solution of step b) until the peptide dissolves in the solution; and
- d) if necessary, adjusting the pH of the solution of step c) to a pH of 4-9, thereby manufacturing the pharmaceutical composition.
22. The process of claim 21, wherein the predetermined concentration of the substituted  $\beta$ -cyclodextrin is such which results in a final concentration of substituted  $\beta$ -cyclodextrin in the pharmaceutical composition of from 70 mg/ml to 170 mg/ml.
23. The process of claim 22, wherein the predetermined concentration of the substituted  $\beta$ -cyclodextrin is such which results in a final concentration of substituted  $\beta$ -cyclodextrin in the pharmaceutical composition of 120 mg/ml.
24. The process of claim 21, wherein the predetermined amount of peptide is such which results in a final concentration of peptide in the pharmaceutical composition of at least 0.1 mg/ml.
25. The process of claim 21, wherein the predetermined amount of peptide is such which results in a final concentration of peptide in the pharmaceutical composition of at least 0.5 mg/ml.
26. The process of claim 21, wherein the predetermined amount of peptide is such which results in a final concentration

of peptide in the pharmaceutical composition of 2.5 mg/ml, 2.0 mg/ml, 1.0 mg/ml, 0.5 mg/ml or 0.1 mg/ml.

27. The process of claim 21, wherein step b) further comprises mixing the solution for 1 hour.
28. The process of claim 21, wherein in step c) the pH is adjusted using HCl or NaOH 1.0N.
29. The process of claim 21, further comprising filtering the solution of step d) through a cellulose acetate filter.
30. The process of claim 21, wherein  
the predetermined concentration of the substituted  $\beta$ -cyclodextrin is such which results in a final concentration of substituted  $\beta$ -cyclodextrin in the pharmaceutical composition of 120 mg/ml;  
the predetermined amount of peptide is such which results in a final concentration of peptide in the pharmaceutical composition of 2.5 mg/ml, 2.0 mg/ml, 1.0 mg/ml, 0.5 mg/ml or 0.1 mg/ml;  
step b) further comprises mixing the solution for 1 hour; and  
in step c) the pH is adjusted using HCl or NaOH 1.0N, further comprising filtering the solution of step d) through a cellulose acetate filter.
31. A pharmaceutical composition prepared by the process of any one of claims 21-30.
32. A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:
  - a) lowering the temperature of the pharmaceutical composition to  $-40^{\circ}\text{C}$ ;

- b) holding the temperature at  $-40^{\circ}\text{C}$  for a predetermined time;
- c) raising the temperature of the solution to  $20^{\circ}\text{C}$ ;
- d) holding the temperature at  $20^{\circ}\text{C}$  for a predetermined time; and
- e) reducing the pressure and holding the temperature at  $20^{\circ}\text{C}$  for a predetermined time, thereby lyophilizing the pharmaceutical composition.

33. The process of claim 32, wherein step a) is performed within 2 hours.

34. The process of claim 32, wherein step b) is performed within 3 hours.

35. The process of claim 32, wherein step c) is performed over 13 hours.

36. The process of claim 32, wherein step c) is performed at a pressure of  $110\mu\text{bar}$ .

37. The process of claim 32, wherein step d) is performed over 13 hours.

38. The process of claim 32, wherein step d) is performed at a pressure of  $110\mu\text{bar}$ .

39. The process of claim 32, wherein in step e) the pressure is reduced to  $10\mu\text{bar}$ .

40. The process of claim 32, wherein step e) is performed over 5 hours.

41. The process of claim 32, wherein  
step a) is performed within 2 hours;

step b) is performed within 3 hours;  
step c) is performed over 13 hours and at a pressure of 110 $\mu$ bar;  
step d) is performed over 13 hours and at a pressure of 110 $\mu$ bar; and  
step e) is performed over 5 hours and the pressure is reduced to 10 $\mu$ bar.

42. A lyophilized pharmaceutical composition prepared by the process of any one of claims 32-41.

43. A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:

- a) lowering the temperature of the pharmaceutical composition to -45°C;
- b) holding the temperature at -45°C for a predetermined time;
- c) raising the temperature of the solution to -20°C;
- d) raising the temperature of the solution to 25°C; and
- e) holding the temperature at 25°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

44. The process of claim 43, wherein step a) is performed within 6 hours.

45. The process of claim 43, wherein step b) is performed within 3 hours.

46. The process of claim 43, wherein step c) is performed over 19 hours.

47. The process of claim 43, wherein step c) is performed at a pressure of 150 $\mu$ bar.

48. The process of claim 43, wherein step d) is performed over 13 hours.

49. The process of claim 43, wherein step d) is performed at a pressure of 150μbar.

50. The process of claim 43, wherein step e) is performed over 8 hours.

51. The process of claim 43, wherein step e) is performed at a pressure of 150μbar.

52. The process of claim 43, wherein  
    step a) is performed within 6 hours;  
    step b) is performed within 3 hours;  
    step c) is performed over 19 hours and at a pressure of 150μbar;  
    step d) is performed over 13 hours and at a pressure of 150μbar; and  
    step e) is performed over 8 hours and at a pressure of 150μbar.

53. A lyophilized pharmaceutical composition prepared by the process of any one of claims 43-52.

54. The lyophilized pharmaceutical composition of claim 53, wherein the water content of the composition is less than 5%.

55. The lyophilized pharmaceutical composition of claim 54, wherein the water content of the composition is less than 4.0%.

56. The lyophilized pharmaceutical composition of claim 55, wherein the water content of the composition is less than 3.5%.

57. A lyophilized pharmaceutical composition comprising



a pharmaceutically acceptable salt of a peptide having the structural formula

NH<sub>2</sub>-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-cooh  
(SEQ ID NO:1); and

a substituted  $\beta$ -cyclodextrin.

58. A packaged pharmaceutical composition comprised of:  
a packaging material; and  
a predetermined amount of the lyophilized pharmaceutical composition of claim 57.